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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-------------------------------|------------------|
| 09/575,480 | 05/19/2000 | Gregory A Kopia | CRD-850 | 1106 |
| 7590 06/02/2004 | | | | |
| Audley A Ciamporcero Jr One Johnson & Johnson Plaza New Brunswick, NJ 08933-7003 | | | EXAMINER ODLAND, KATHRYN P | |
| | | | ART UNIT 3743 | PAPER NUMBER |
| DATE MAILED: 06/02/2004 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 09/575,480 | Applicant(s) KOPIA ET AL. | |
| | Examiner Kathryn Odland | Art Unit 3743 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/00, 1/01, 5/03, 4/24/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

This is a response to the amendment dated April 23, 2004. Claims 1 and 3-9 are pending.

1. Applicant's arguments with respect to claims 1 and 3-9 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claim 1 recites the limitation "said layers" in line 5. There is insufficient antecedent basis for this limitation in the claim. Any art rejection is as best understood.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 3, 4 and 6 are rejected under 35 U.S.C. 102(a and/or e) as being anticipated by Kamath et al. in US Patent No. 6,335,029.

Regarding claim 1, Kamath et al. disclose a process for the treatment of restenosis via intravascular infusion or delivery by release from a surface of a stent of a combination of at least two agents, as recited in column 3, lines 63-67, column 5, lines 5-18, column 6 and column 7. Further, the at least two agents include an anti-proliferative agent, as recited in column 5, lines 58-62 and column 6, lines 5-10 which will inhibit smooth muscle cell growth. The anti-proliferative is rapamycin or an analogue, as recited in column 6, lines 20-25 where TAXOL is considered the analogue – consistent with claims 5 and 7 of the current application. Further, Kamath et al. disclose at least two agents that include an anti-inflammatory, as recited in column 5, lines 55-58 and column 6, lines 5-11 that will inhibit smooth muscle growth in therapeutic dosage amounts. They are in layers in therapeutic dosages, as recited in column 5, lines 5-20 and column 7, lines 40-45.

Regarding claim 3, Kamath et al. disclose that as applied to claim 1, as well as, an anti-inflammatory agent that is dexamethasone and an anti-proliferative that is taxol, as recited in column 5, line 58 and column 6, lines 13-27.

Regarding claim 4, Kamath et al. as modified disclose that as applied to claim 1, as well as, a combination of at least two agents that include a growth factor, as recited in column 5, lines 63-67.

Regarding claim 6, Kamath et al. disclose that as applied to claim 1, as well as, a combination of at least two elements that include a tyrosine kinase inhibitor, as recited in column 5, lines 60-64.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kamath et al. in US Patent No. 6,335,029 in view of End.

Kamath et al. disclose the invention as applied to claims 1. However, Kamath et al. do not explicitly recite R11577. On the other hand, End teaches the ras inhibitor, R11577. Therefore, it would be obvious to one with ordinary skill in the art modify the invention of Kamath et al. to include R115777 as a signal transduction inhibitor for the purpose of increasing antiproliferation. Moreover, it is improper to include codes in the claims; the compositions should be explicitly recited.

8. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kamath et al. in US Patent No. 6,335,029 in view of Levitzki et al. in US Patent No. 5,932,580.

Kamath et al. disclose the invention as applied to claim 1. However, Kamath et al. do not explicitly recite tyrphostin as a tyrosine inhibitor. However, Levitzki et al. teach of tyrphostin, as recited in column 5, lines 35-67, column 6, and column 8. Therefore, since implantation is a method of administration as recited in column 8, line 67, it would be obvious to one with ordinary skill in the art at the time the invention was made to modify the invention of Kamath et al. to include a the tyrosine inhibitor of tyrphostin to suppress SMC.

9. Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamath et al. in US Patent No. 6,335,029 in view of Nagler et al. in US Patent No. 6,159,488.

Kamath et al. disclose the invention as applied to claim 1. However, Kamath et al. do not explicitly recite halofuginone as an inhibitor of extracellular matrix. On the other hand, Nagler et al. teach a stent coated with halofuginone, as recited in column 9 and column 10. Therefore, it would be obvious to one with ordinary skill in the art at the time the invention was made to modify the system of Kamath et al. to include halofuginone for the purpose of inhibiting SMC proliferation.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

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1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1 and 3-9 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 and 25 of copending Application No. 09/850,482. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely reworded representations for identical subject matter. In some aspects some limitations are broader while others are more specific.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

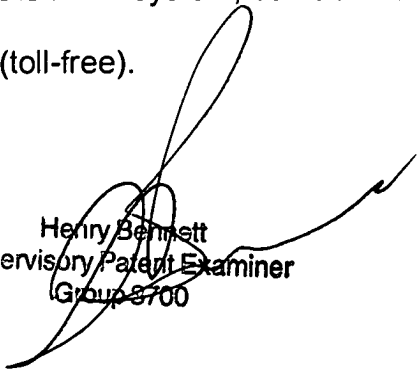
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KO



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